REMARKS

I. Status of Claims

Claims 37-43, 45-57, and 59-62 are currently pending. Claim 52 is currently amended and claims 44 and 58 are canceled without prejudice to or disclaimer of the subject matter therein. Claims 59-62 are newly added.

Claims 37-39, 41-44, 46-48, 52, and 54-57 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,203,551 to Wu (hereinafter "Wu") in view of U.S. Patent No. 4,598,006 to Sand (hereinafter "Sand"). Claims 37-39, 41-44, 46-48, 52, and 54-57 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sand in view of Wu. Claims 37-39, 41-44, 46-48, 52, and 54-57 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sand in view of Wu, and further in view of U.S. Patent No. 5,527,337 to Stack et al. (hereinafter "Stack"). Claims 40, 48, and 49 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sand/Wu/Stack, and further in view of U.S. Patent No. 6,627,246 to Mehta et al. Claims 45, 50, 51, 53, and 58 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sand/Wu/Stack, and further in view of U.S. Patent No. 6,495,204 to Allen et al.

The Applicant respectfully requests reconsideration of the rejections in view of the following remarks.

II. Double Patenting

Claim 44 is canceled, thus obviating the double patenting rejection.

III. Pending Claims

Claims 37 and 52 are the only independent claims. These claims stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over various combinations of Wu, Sand and Stack. These claims are generally directed to a three-step process summarized as follows: (1) a coating step; (2) a swelling step in which the coating is swollen with a SCF devoid of therapeutic; and (3) a separate interfacing step in which a medical device is exposed to SCF interfaced with therapeutic.

More specifically, the claims are reproduced in their entirety as follows:

37. A method of treating a coating of a stent comprising:

precoating the stent with a swellable carrier coating;

temporarily swelling the carrier coating with a supercritical fluid devoid of therapeutic prior to providing a supercritical fluid carrying a therapeutic;

causing the stent, with the swollen carrier coating, to be in contact with the supercritical fluid carrying the therapeutic. (emphasis added)

52. A method of treating a coating of a medical device comprising:

coating the medical device;

interfacing a therapeutic with a first supercritical fluid; and,

temporarily swelling the coating on the medical device with a second supercritical fluid devoid of coating and therapeutic prior to exposing the coating on the coated medical device to the first supercritical fluid, which has been interfaced with the therapeutic. (emphasis added)

The Applicant respectfully submits that the Office Action has not addressed each and every limitation of the independent claims.

a. The Present Application

As discussed in paragraphs [0026] and [0027] of the application as published, with reference to FIG. 3, certain embodiments of the present application regard a coating system 30 having a first supercritical fluid tank 34, a second supercritical tank 37, a therapeutic tank 33, a coating chamber 32, and a support 39, which may be rotatable in the direction of arrow 391. The coating system may contain a recycling chamber 31,

In use, after the stent 36 has been placed on the support 39, the second supercritical fluid tank 37 may be used to flood the coating chamber 32 with a supercritical fluid and, thus, swell the coating 35 resident on the surface of the stent 36. Then, after the coating 35 has swelled, the

supercritical fluid resident within tank 34, which has been previously mixed with therapeutic from tank 33, may be released into the chamber 32. An advantage of swelling the coating before exposing it to the therapeutic is that the coating may be better able to receive the therapeutic due to its enlarged state. For example, as seen in FIG. 3, coating line 38 illustrates the degree to which the original coating 35 may swell when exposed to certain supercritical fluids.

b. The Wu Reference

By the Examiner's own admission, Wu fails to teach a process that uses a supercritical fluid (hereinafter "SCF") as a solvent in a swell loading process comprising swelling the polymer with a swelling agent devoid of a therapeutic. See ¶ 4 of the June 26, 2006 Office Action.

c. The Sand Reference

In an attempt to cure this deficiency, the Office Action cites Sand. The Applicant respectfully submits that Sand does not disclose temporarily swelling coating with a SCF devoid of coating. Sand discloses a method for impregnating a thermoplastic polymer with an "impregnation material" such as a fragrance, pest control agent, or pharmaceutical composition.

The undersigned carefully reviewed Sand and found no discussion of swelling a coating with a SCF devoid of therapeutic. For example, the Abstract of Sand states, "(2) swelling the thermoplastic polymer by contacting it at or near supercritical conditions for the volatile swelling agent with the impregnation material…" (emphasis added). Next, column 3, lines 60-64, of Sand states, "[t]he thermoplastic polymer is swollen by contacting it at or near supercritical conditions with the fragrance, pest control agent, or pharmaceutical impregnation material-laden swelling agent." (emphasis added). Further, lines 37-39 of column 4, line 25 of column 5, and claim 1 of the Sand specification all reference swelling agents laden with impregnation materials.

In other words, Sand does not discuss or disclose a swelling step using a SCF devoid of therapeutic as in the present application.

d. The Stack Reference

In another attempt to cure the deficiencies of Wu, the Office Action cites Stack. The portion of Stack relied upon in the Office Action, states:

"Other methods can also be used to incorporate drugs into the stents of the present invention. For example, small water soluble particulates can be added to the polymer before extrusion and leached out post-fabrication to create pores. Monomeric lactide can be incorporated before extrusion and subsequently leached out. Very small pores can be created by swelling the polymer at any stage post-extrusion in a SCF such as propane and then reducing the pressure so that no liquid phase exists. In all cases, drug containing solutions can be forced into the pores by hydrostatic pressure with or without a gelling agent to control out-diffusion of the drug." See col. 12, lines 4-10.

Although this passage discusses swelling a polymer with a SCF such as propane, it does not address temporarily swelling a coating with a SCF devoid of therapeutic as claimed in the present application. Rather, this cited passage of Stack addresses the permanent creation of very small pores in a polymer that will comprise a stent. A coating is not discussed in the passage and the material that swells is not exposed to a SCF interfaced with therapeutic while swollen. Therefore, modifying Wu and/or Sand with the teachings of Stack still does not arrive at the invention as claimed by the Applicant.

Further, the Applicant respectfully submits that it is necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed by the Applicant. More specifically, it is necessary to identify why a person of ordinary skill in the art would have been prompted to combine the elements in the manner claimed by Applicant.

The Applicant respectfully submits for at least these reasons, claims 37 and 52, as well as their dependent claims are patentable over the cited references.

IV. Conclusion

In view of the above amendments and remarks, it is believed that the above-identified application is in condition for allowance, and notice to that effect is respectfully requested. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned at the telephone number indicated below.

The Commissioner is authorized to charge any fees or credit any overpayments which may be incurred in connection with this paper under 37 C.F.R. §§ 1.16 or 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

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